

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

EILEEN WAWRZYNEK and	:	CIVIL ACTION
JOSEPH WAWRZYNEK,	:	
Plaintiffs	:	
	:	
v.	:	
	:	
STATPROBE, INC., <i>et al</i> ,	:	
Defendants	:	NO. 05-1342

**MEMORANDUM AND ORDER**

Gene E.K. Pratter, J.

September 2, 2005

This litigation concerns a claim that Defendant Statprobe, Inc., and the other Defendants who are successor corporations to Statprobe (collectively referred as “Statprobe”), are liable to Plaintiff Eileen Wawrzynek for breach of contract, fraud, and negligence by removing the double-blind parameters from a study related to ADCON-L and providing the “unblinded” data, rather than the original blind data, to the Federal Drug Administration (“FDA”). Plaintiff Joseph Wawrzynek is claiming damages for loss of consortium. The inaccurate study, according to Plaintiffs, allowed the product ADCON-L to be approved by the FDA and used by Ms. Wawrzynek’s surgeon during her back surgery. Plaintiffs assert that ADCON-L caused an infection in Ms. Wawrzynek’s back leading her to suffer severe decomposition of her spinal column. Statprobe seeks dismissal of the Complaint.

In its Motion to Dismiss, Statprobe asserts that Plaintiffs’ claims are barred by the relevant statutes of limitation. Alternatively, Statprobe asserts that Plaintiffs are not third party beneficiaries of the agreement between Statprobe (a bioanalysis company) and Gliatech, Inc., the manufacturer of ADCON-L, so Plaintiffs have no standing to bring a breach of contract claim. Further, Statprobe claims that because it did not owe Plaintiffs a duty of care, the negligence

claim fails as a matter of law.

For the reasons discussed below, the Motion to Dismiss is denied in part and granted in part. The Motion is granted as to the breach of contract claim, and that claim is dismissed. As to all other arguments in the Motion, the Motion is denied.

**I. SUBJECT MATTER JURISDICTION**

Statprobe removed this case to federal court based on diversity jurisdiction pursuant to 18 U.S.C. §§ 1441 and 1446. Plaintiffs are citizens of Pennsylvania. All of the Defendants are corporations that are incorporated outside of Pennsylvania and have their principal place of business outside of Pennsylvania. The amount in controversy is alleged to be over \$75,000.

**II. FACTUAL BACKGROUND**

Because this is a motion to dismiss, the Court will recount the facts as alleged in the Complaint. These facts will be presumed true for the purpose of this Motion.

Statprobe is in the business of providing comprehensive data services for manufacturers of drugs and medical devices seeking FDA approval. (Pls.' Compl., at ¶ 9). Statprobe entered into a contract with Gliatech, Inc., a medical device manufacturer, to provide bio-statistical services for an IDE Clinical Study titled "A Randomized Controlled Double-Blind Multi-Center Study to Evaluate the Safety and Effectiveness of ADCON-L for Inhibition of Post-Operative Peridural Fibrosis Following Spinal Root Decompression."<sup>1</sup> (Pls.' Compl., at ¶ 14). In the contract Statprobe agreed to assist Gliatech in compliance responsibility for the clinical study and perform the study in accordance with applicable laws and regulations. (Pls.' Compl., at ¶ 15).

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<sup>1</sup> This study was to include 365 patients, half of whom were given ADCON-L and half who were not. ADCON-L was supposed to inhibit the formation of scar tissue following single level lumbar disc surgery. (Pls.' Compl., at ¶ 17).

The study was initiated on January 19, 1996 and completed in November 1997. (Pls.' Compl., at ¶ 16).

On May 27, 1998, the FDA gave conditional approval to Gliatech to manufacture and distribute ADCON-L. (Pls.' Compl., at ¶ 18). One of the conditions of approval was that "a final report for your US clinical trial... must be provided within three months of study completion... failure to comply with the conditions of approval invalidates this approval order." (Pls.' Compl., at ¶ 18).

On July 19, 1997, Statprobe became aware of irregularities with respect to the ADCON-L studies, including data manipulation, and requested its name not be used on reports or presentations. (Pls.' Compl., at ¶ 21). By November 1997, the study was completed and Statprobe informed Gliatech that the data failed to show that the product was effective. (Pls.' Compl., at ¶ 22). On January 12, 1998, following Gliatech's request, Statprobe provided Gliatech the code to "unblind" the status of patients in the treatment and control groups. (Pls.' Compl., at ¶ 23). Gliatech personnel performed a second reading of the studies that changed some of the data in a manner that made ADCON-L appear more effective. (Pls.' Compl., at ¶ 25).

Gliatech provided this new data to Statprobe, which accepted the new study and altered its report to show that ADCON-L was effective. (Pls.' Compl., at ¶ 27). Statprobe insisted on payment prior to accepting this new data. (Pls.' Compl., at ¶ 28). Statprobe failed to reveal in the final report that the study was unblinded, that some data was changed, and that the original study had found the product ineffective. (Pls.' Compl., at ¶¶ 30-32). After receipt of this final study, the FDA approved Gliatech's continued marketing of ADCON-L. (Pls.' Compl., at ¶ 33).

The study also revealed that approximately 2% of the patients who used ADCON-L developed leaks of CSF fluid through the dura following surgery, while none of the control patients developed such leaks. (Pls.' Compl., at ¶ 35).

On February 18, 1999, Ms. Wawrynek underwent lumbar surgery. (Pls.' Compl., at ¶ 37). During the surgery, a minute injury to the dura was discovered and repaired, and Ms. Wawrynek's surgeon applied ADCON-L to the operative site. (Pls.' Compl., at ¶ 38). The leak did not heal, and Ms. Wawrynek underwent a second surgery and developed some complications from the leak. (Pls.' Compl., at ¶¶ 39-41).

In December 2000, Plaintiffs sued Ms. Wawrynek's surgeon. On July 2, 2002, Plaintiffs sued Giatech.<sup>2</sup> (Pls.' Compl., at ¶ 44). Although Giatech was then in bankruptcy, Plaintiffs were able to circumvent the bankruptcy stay in order to engage in discovery in which 20 CDs containing 200,000 individual documents were provided for the time period between October 15, 2003 and November 26, 2003. (Pls.' Compl., at ¶¶ 47-48). During this discovery activity, Plaintiffs became aware of Statprobe's involvement and "fraudulent concealment of its improper conduct." (Pls.' Compl., at ¶ 49). Plaintiffs allege that they could not have determined Statprobe's "identity, conduct and fraudulent concealment prior to review of the CDs which plaintiffs did not obtain until the October-November 2003 time frame." (Pls.' Compl., at ¶ 50).

Plaintiffs allege three counts against Statprobe, Count One for negligence; Count Two for fraud; and Count Three for breach of contract.

<sup>2</sup> On March 29, 2002, Giatech pleaded guilty to a six-count information charging the company with four counts of failure to notify the FDA of reportable events occurring in medical procedures; one count of adulteration of a medical device; and one count of submission of a report regarding a medical device that was false and misleading in a material respect. (Pls.' Compl., at ¶ 42).

### **III. LEGAL STANDARD**

When deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court may look only to the facts alleged in the complaint and its attachments. Jordan v. Fox, Rothschild, O'Brien & Frankel, 20 F.3d 1251, 1261 (3d Cir. 1994). The Court must accept as true all well-pleaded allegations in the complaint and view them in the light most favorable to the plaintiff. Angelastro v. Prudential-Bache Sec., Inc., 764 F.2d 939, 944 (3d Cir. 1985). A Rule 12(b)(6) motion will be granted only when it is certain that no relief could be granted under any set of facts that could be proved by the plaintiff. Ransom v. Marrazzo, 848 F.2d 398, 401 (3d Cir. 1988).

### **IV. DISCUSSION**

#### **A. Statute of Limitations**

Under the Pennsylvania statute of limitations, a plaintiff is time-barred if she does not file negligence or fraud claims within two years of injury or a breach of contract claim within four years of injury. 42 PA. CONS. STAT. ANN. §§ 5524-25. Under the “discovery rule,” the statute of limitations is tolled until a plaintiff “knew or should have known on the exercise of reasonable diligence of his injury and its cause.” Fine v. Checcio, 870 A.2d 850, 858 (Pa. 2005). The question of when a plaintiff “should have known on the exercise of reasonable diligence of his injury and its cause” is a question for the jury. Id. at 859. A party asserting the discovery rule “bears the burden of establishing the inability to know of the injury despite the exercise of reasonable diligence.” Dalrymple v. Brown, 549 Pa. 217, 224 (Pa. 1997). Reasonable diligence is defined as “a reasonable effort to discover the cause of an injury under the facts and circumstance present in the case.” Cochran v. GAF Corp., 666 A.2d 245, 249 (Pa. 1995).

A party's fraudulent concealment of its action or identity also will toll the statute of limitations. Ciccarelli v. Carey Can. Mines, Ltd., 757 F.2d 548, 556 (3d Cir. 1985). Fraudulent concealment is based on estoppel and "provides that a defendant may not invoke the statute of limitations if, through fraud or concealment, he caused the plaintiff to relax his vigilance or deviate from his right of inquiry into the facts." Drelles v. Manufacturers Life Ins. Co., 2005 WL 1545533, at \*6 n.6 (Pa. Super. Ct. July 5, 2005). Fraudulent concealment "does not require fraud in the strictest sense encompassing an intent to deceive, but rather, fraud in the broadest sense, which includes an unintentional deception." Fine, 870 A.2d at 860. However, the standard of reasonable diligence applies equally to the doctrine of fraudulent concealment as to the "discovery rule," so "a statute of limitations that is tolled by virtue of fraudulent concealment begins to run when the injured party knows or reasonably should know of his injury and its cause." Id. at 861. In other words, to prove fraudulent concealment, a plaintiff must allege that the defendant concealed, either intentionally or unintentionally, the existence of the injury or the cause and that plaintiff would not have discovered the injury or cause with reasonable diligence. These allegations must be "stated with particularity." FED. R. CIV. P. 9(b); Byrnes v. DeBolt Transfer, Inc., 741 F.2d 620, 626 (3d Cir. 1984).

Statprobe contends that neither the discovery rule nor fraudulent concealment apply to this matter, and the statutes of limitation should not be tolled. According to Statprobe, Plaintiffs do not enumerate what actions Statprobe took to fraudulently conceal its identity or specify any facts to support the claim. Instead, Statprobe argues, Plaintiffs make unsubstantiated accusations of fraudulent concealment. Additionally, Statprobe asserts that even if there was initial fraudulent concealment, Plaintiffs did not exercise reasonable diligence to ascertain the cause of

Ms. Wawrynek's injury. Statprobe notes that the allegedly serious spinal injury was detected by the second surgery in February 2000. By 2002, Plaintiffs were aware of Giatech's involvement (as demonstrated by their filing of a complaint against Giatech), and, Statprobe contends, through the exercise of reasonable diligence Plaintiffs would have known of Statprobe's relationship with Giatech and involvement in the clinical study. Finally, Statprobe notes that a recent Pennsylvania Superior Court decision held that when an injury is known, neither the discovery rule nor possible fraudulent concealment by defendants absolve plaintiffs of diligently pursuing their claim after injury. Meehan v. Archdiocese of Philadelphia, 870 A.2d 912, 920 (Pa. Super. Ct. 2005).

Plaintiffs respond that, even exercising reasonable diligence, it was impossible for them to discover Statprobe's involvement until the documents provided in the Giatech discovery were produced. Further, Plaintiffs contend that Statprobe concealed its negligent behavior by submitting falsified information to the FDA and that the Complaint sufficiently alleged this fraud to satisfy the requirements of Rule 9(b). According to Plaintiffs, because reasonable diligence is the relevant issue under either the discovery rule or the doctrine of fraudulent concealment, the statutes of limitation were tolled until October 2003, when Plaintiffs first could have reasonably discovered Statprobe's involvement.

From the Complaint, it would appear that Statprobe's name was not publicly connected to the ADCON-L trials, leaving a question whether reasonable diligence would have revealed this information prior to the discovery activity looking into Giatech's alleged negligence. Further, even if Statprobe was known to be involved in the original study, the Complaint avers facts that could lead a reasonable juror to conclude that Plaintiffs had no way of knowing Statprobe's

alleged actionable conduct prior to Plaintiffs' receipt of the discovery material in October 2003. Therefore, a reasonable interpretation in the light most favorable to the Plaintiffs is that the Complaint alleges facts that would allow a reasonable jury to conclude that reasonable diligence would not reveal Statprobe's involvement until after discovery was underway in the Gliatech matter. Therefore, a Motion to Dismiss will not be granted here on the basis of a statute of limitations argument in light of Fine and Cochran holdings that the question of when reasonable diligence would have made the injury and its cause known to a party is a matter for determination by the jury.

As to the possible tolling under the doctrine of fraudulent concealment, the Court must determine if sufficient facts were alleged in the Complaint to satisfy the requirements under Rule 9(b) and if these facts create an inference that Statprobe concealed its possible involvement or role in events leading to Ms. Wawrynek's injuries. Although the federal rules require specificity when alleging any form of fraud, this demand for specificity only requires that Plaintiffs aver facts that give rise to a "strong inference of fraudulent intent." IUE AFL-CIO Pension Fund v. Herrmann, 9 F.3d 1049, 1057 (2d Cir. 1993). In this case, the Plaintiffs allege that Statprobe willingly provided inaccurate information to the FDA, (Pls.' Compl., at ¶¶ 30-32), while attempting to keep its name off reports or presentations by Gliatech, (Pls.' Compl., at ¶ 21). Further, Plaintiffs claim that, by providing the false and misleading information, Statprobe concealed the problems with ADCON-L, so any attempt by Plaintiffs prior to their Gliatech lawsuit would have revealed only the faulty report. These alleged facts, along with additional facts recounted in the Complaint, are sufficient to satisfy the requirements of the Federal Rules of Civil Procedure regarding pleading fraud with particularity and produce a reasonable inference

that Statprobe, either intentionally or unintentionally, hid its alleged involvement in the injury of Ms. Wawrynek. Fed. R. Civ. Pro. 9(b).

#### **B. Third Party Beneficiary**

Under Pennsylvania law, a party can only establish third-party beneficiary status “where both parties to the contract express an intention to benefit the third party in the contract itself..., unless, the circumstances are so compelling that recognition of the beneficiary’s right is appropriate to effectuate the intention of the parties, and the performance satisfies an obligation of the promisee to pay money to the beneficiary or the circumstances indicate that the promisee intends to give the beneficiary the benefit of the promised performance.” Scarpitti v. Weborg, 609 A.2d 147, 150-51 (Pa. 1992) (emphasis in original; citations omitted). Pennsylvania courts have used a two-part test to determine whether a party is a third-party beneficiary: (1) the recognition of the beneficiary’s right must be “appropriate to effectuate the intention of the parties,” and (2) the performance must “satisfy an obligation of the promisee to pay money to the beneficiary” or “the circumstances indicate that the promisee intends to give the beneficiary the benefit of the promised performance.” Guy v. Liederbach, 459 A.2d 744, 751 (Pa. 1983).

Statprobe argues that the “intended beneficiary” prong is strictly construed. See Marsteller Cnty. Water Auth. v. P.J. Lehman Eng’rs, 605 A.2d 413, 416 (Pa. Super. Ct. 1992) (holding “the fact that the obligee knows that he will perform the contracted-for services for a third party is not, in itself, sufficient to vest the third party with standing to sue on the contract”); Manor Junior College v. Kallers Inc., 507 A.2d 1245, 1248 (Pa. Super. Ct. 1986) (finding that an oral contract between a contractor and subcontractor to install a new roof because there was no

evidence that the subcontractor intended the college to be a beneficiary of the contract).<sup>3</sup>

Statprobe further asserts that members of the public injured as a consequence of a breach of contract are also not *de facto* third-party beneficiaries. See Hicks v. Metropolitan Edison Co., 665 A.2d 529, 535 (Pa. Commw. Ct. 1995) (stating “[w]hile it is true that a third party beneficiary need not be expressly named in the contract so long as the circumstances indicate that the contracting parties intended to confer a benefit... [the plaintiff] would have us expand this concept to include virtually every member of the public” where a bystander alleged he was a third party beneficiary to a services contract between a company who inspected telephone poles and the utility company);<sup>4</sup> Holmes v. Lankenau Hosp., 627 A.2d 763, 771 (Pa. Super. Ct. 1993) (stating “even if it were the intention of the parties to release everyone in the world who might also be liable to the releasor, it is questionable that such a broadly defined class of persons or entities would qualify for third party status”). Statprobe contends that Plaintiffs have not alleged that Ms. Wawrzynek was an intended beneficiary of Statprobe’s contract with Giatech or that all users of ADCON-L were intended beneficiaries. According to Statprobe, simply because Plaintiffs contend that Statprobe “knew or should have known” that Ms. Wawrzynek may be

<sup>3</sup> Plaintiffs contend that the Superior Court in Manor Junior College found that third-party beneficiary status was unavailable when there is an oral argument between the parties. However, the Superior Court held, after reviewing the testimony of the defendant regarding the terms of the contract: “Therefore, the finding is inescapable that Spencer did not in his agreement with Kaller intend the college as a beneficiary, and the conclusion necessarily follows that the college was not a third party beneficiary of the contract between Kaller and Spencer.” Manor Junior College, 507 A.2d at 1248. Thus, it appears that the Pennsylvania Supreme Court considered the possibility of third party beneficiary status emanating from an oral contract.

<sup>4</sup> Plaintiffs argue that Hicks analysis does not apply here, because Plaintiffs are only asserting that recipients of ADCON-L were third-party beneficiaries, not “virtually every member of the public.”

affected if Statprobe breached its contractual responsibilities does not make Ms. Wawrzynek an intended beneficiary.

Plaintiffs note that the contract between Statprobe and Gliatech incorporated the terms of the federal regulations with respect to medical devices. These regulations explicitly state that the FDA will release information concerning safety and effectiveness to the public. Therefore, according to Plaintiffs, Ms. Wawrzynek and other users of ADCON-L were the intended beneficiaries of the contract, inasmuch as they are members of the public who Statprobe was contractually obligated to properly inform. Plaintiffs cite to two cases that hold that plaintiffs who have valid claims against an insured are third party beneficiaries of the contracts between the insurance companies and the insured. Apalucci v. Agora Syndicate, Inc., 145 F.3d 630, 634 (3d Cir. 1998) (“an insurance company’s failure to defend its insured, which results in the entry of a default judgment against the insured, entitles a third-party beneficiary of a liability insurance policy to directly sue the insurer to collect and enforce the default judgment”); Solter v. Health Partners of Philadelphia, 215 F.Supp.2d 533, 539 n.8 (E.D. Pa. 2002) (“a contract exists between the [insured] and the [insurance company] requiring the latter to provide medically necessary services. Plaintiff is a third-party beneficiary to this contract. Thus plaintiff can enforce her rights to ‘medically necessary’ care with a breach of contract claim against [the insurance company], the exact path plaintiffs have taken in this case”).<sup>5</sup>

Under Pennsylvania law, the first prong of the test to determine if a party is a third party beneficiary is whether a third party beneficiary was intended by the contract. In this case,

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<sup>5</sup> Statprobe argues that these cases do not apply to the current situation, because Statprobe was not an insurer that knew its insureds would have claims against it. Statprobe’s contract was to provide biostatistical services, not to insure.

Plaintiffs have not cited to any language in the contract between Gliatech and Statprobe that demonstrates an intention by those parties to have any third party benefit from the contract.

Plaintiffs here are indeed stretching the bounds of who would be considered a third party beneficiary under Pennsylvania law. It is difficult to see how a party entering into a contract to provide research services would be intending to provide benefit to any and all potential users of the product under study.

Plaintiffs cite to a series of cases that discuss the applicability of the third party beneficiary status to insurance contracts. These cases are not applicable to this situation because liability insurance contracts clearly “intend” for the insurer to pay a third party some obligation due by the insured. In this case, the contract between Gliatech and Statprobe was a “service contract” that did not intend for anybody but Gliatech to benefit from Statprobe’s work.

As the Pennsylvania Commonwealth Court stated in Hicks: “while it is true that a third party beneficiary need not be expressly named in the contract so long as the circumstances indicate that the contracting parties intended to confer a benefit... [the plaintiff] would have us expand this concept to include virtually every member of the public.” Hicks, 665 A.2d at 535. Similarly, because, prior to ADCON-L being pulled from the market, any member of the public may have used ADCON-L, Plaintiffs here would have the Court redefine the “intent” prong of the third party beneficiary test to include “virtually every member of the public.” This Court will not so expand the definition of third-party beneficiary simply because, significantly after the contract is executed, Plaintiffs can describe a subset of the general public that was, in this case, harmed by Statprobe’s alleged breach of the contract. Plaintiffs have the burden of alleging facts that show that Gliatech and Statprobe intended to benefit Plaintiffs, and similarly situated

individuals, when they executed the contract at issue. Plaintiffs have failed to meet this burden, and the Court grants the Motion to Dismiss as to the breach of contract claim.

### C. Negligence

Under Pennsylvania law, to make a claim for negligence, a plaintiff must plead: “the existence of a duty or obligation recognized by law; a failure on the part of the defendant to conform to that duty, or a breach thereof; a causal connection between the defendant's breach and the resulting injury; and actual loss or damage suffered by the complainant.” Orner v. Mallick, 527 A.2d 521, 523 (Pa. 1987). The question of whether a legal duty exists is a question of law reserved for the trial court. Sharpe v. St. Luke's Hosp., 821 A.2d 1215, 1219 (Pa. 2003).

Statprobe contends that it did not owe Ms. Wawrzynek a duty of care. Statprobe cites to Staples v. Merck & Co., Inc., 270 F. Supp. 2d 833 (N.D. Tex. 2003), in which the District Court for the Northern District of Texas found that, in Texas, “generally, independent laboratories have no duty of reasonable care toward parties with which they did not contract.” Staples, 270 F. Supp. 2d at 838.<sup>6</sup> Further, Statprobe cites to a series of cases where independent laboratories, that were performing drug testing for employers, had no legal duty to the employees with whom they had no contract and no personal contact. Tricoski v. Lab. Corp. of America, 216 F. Supp. 2d 444, 445 (E.D. Pa. 2002); Hammond v. City of Philadelphia, 164 F. Supp. 2d 481, 483 (E.D. Pa. 2001); Ney v. Axelrod, 723 A.2d 719, 721-22 (Pa. Super. Ct. 1999). However, for example,

<sup>6</sup> The court did note an exception to this general rule if the laboratory “created a ‘dangerous situation.’” Staples, 270 F. Supp. 2d at 838. The court also stated that when making this determination the court must “focus exclusively on the Plaintiffs and the Clinical Researchers, and disregard either party’s relationship” with the manufacturer of the product. Id. Plaintiffs distinguish this case by noting that in Staples the clinical researcher accurately reported the data, but in this case, Statprobe was the entity that directly assisted in manipulation of data by “unblinding” the study and substituting false data for the original data.

when hospital personnel personally took a urine sample, that can create a “sufficient relationship” to create a duty between the hospital and the plaintiff. Sharpe, 821 A.2d at 1219. In comparison, Statprobe argues that it is even more remote from the actionable conduct than the laboratories performing drug tests, and, rather, is in the same situation as the clinical researchers in Staples, where the work done was the compilation of data from neuroradiologists and the preparation of a study.

Plaintiffs make several counter arguments to demonstrate that Statprobe owed a duty of care to Ms. Wawrynek. First, according to Plaintiffs, the Complaint alleges sufficient facts that Statprobe negligently misrepresented the efficacy of ADCON-L by assisting in the doctoring of the trials and this misrepresentation created a risk of physical harm to recipients of ADCON-L.<sup>7</sup> Plaintiffs note the standard for negligent misrepresentation found in Restatement (Second) of Torts § 311<sup>8</sup> and argue that Statprobe is liable for negligently misrepresentation by providing false information to the FDA which directly led to Ms. Wawrynek’s injury. Plaintiffs further

<sup>7</sup> Statprobe notes in its Reply, first, that Plaintiffs did not raise negligent misrepresentation in their Complaint, and, second, that all the facts in the Complaint demonstrate is that Statprobe’s alleged misrepresentation resulted in ADCON-L being considered as effective when it was ineffective, not that Statprobe assisted in allowing a *dangerous* product to remain on the market.

<sup>8</sup> § 311. Negligent Misrepresentation Involving Risk of Physical Harm

(1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results

- (a) to the other, or
- (b) to such third persons as the actor should expect to be put in peril by the action taken.

(2) Such negligence may consist of failure to exercise reasonable care

- (a) in ascertaining the accuracy of the information, or
- (b) in the manner in which it is communicated.

RESTATEMENT (SECOND) OF TORTS § 311.

argue that Statprobe assumed a statutory obligation to provide accurate information and to inform the public of the results of the study it compiled with respect to ADCON-L's effectiveness.<sup>9</sup>

According to Plaintiffs, this assumed statutory obligation means that Statprobe owed a duty of care to Ms. Wawrynek and any other members of the public who were treated with ADCON-L.

Second, Plaintiffs argue that Statprobe also violated its duties to Plaintiffs by negligently undertaking<sup>10</sup> its research when Statprobe unblinded the study and perpetrated a fraud upon the

<sup>9</sup> Plaintiffs cite to Gutzan v. Altair Airlines, Inc., 766 F.2d 135 (3d Cir. 1985), in which they claim the Court of Appeals for the Third Circuit affirmed the submission of the case to jury under causes of action for negligence and the duty not to transmit false information. However, upon closer reading of Gutzan it is clear that the Court of Appeals actually was responding to an appeal by the Plaintiff that the jury instruction was inadequate and the trial court erred by "refusing to instruct the jury on negligent misrepresentation and negligent performance of an undertaking as set forth in sections 324A and 311 of the Restatement Second of Torts." Gutzan, 766 F.2d at 138. The Court found:

Although the instructions are not a model of clarity and particularity, they do inform the jury of the duty one owes, by virtue of his relationship to a person, to protect that person from unreasonable risk of harm, and in this respect not to act negligently. The instructions explain the concepts of duty, negligence, negligent omission, proximate cause, and preponderance of the evidence. There is nothing in the charge that would lead the jury to conclude that one who negligently gives false information to a party may not be liable for physical harm to a third party caused by action taken by the recipient of the information in reasonable reliance on it.

*Id.* at 139. Thus, Gutzan does not supply the unambiguous support of Plaintiffs' argument on this point as they urge.

<sup>10</sup> Pennsylvania has adopted the Restatement (Second) of Torts regarding negligent undertaking, which states:

§ 324A. Liability to Third Person for Negligent Performance of Undertaking  
One who undertakes ... to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if  
(a) his failure to exercise reasonable care increases the risk of such harm, or  
(b) he has undertaken to perform a duty owed by the other to the third person, or  
(c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

RESTATEMENT (SECOND) OF TORTS § 324(a).

public. Plaintiffs cite to two cases where healthcare providers were found to have such a duty to third parties despite not having a patient-physician relationship. DiMarco v. Lynch Homes, Inc., 583 A.2d 422, 424-25 (Pa. 1990) (finding third person has cause of action against physician if plaintiff's health is likely to be threatened by physician's patient when physically intimate with patient, patient has communicable disease, and erroneous advice was given to that patient by physician); Troxel v. A. I. DuPont Inst., 675 A.2d 314, 319 (Pa. Super. Ct. 1996) (holding "the duty of the physician treating a patient with a communicable disease is to prevent the spread of the disease, not for the benefit of the patient, whose health has already been compromised, but for the benefit of those third parties" who could foreseeably be harmed). Plaintiffs argue that, as in these cases, Statprobe undertook a service necessary for the protection of others, namely the accurate reporting of data to the FDA, and Statprobe's failure to properly perform this undertaking creates a duty to third parties harmed as a result of Statprobe's negligent undertaking. According to Plaintiffs, the cases cited by Statprobe involving drug testing are not applicable because, unlike those testing companies, Statprobe had a statutory duty to accurately report information to the public.<sup>11</sup>

Third, Plaintiffs contend that Statprobe assumed Gliatech's responsibility to comply with FDA regulations with respect to the study referenced in the contract. Because Pennsylvania recognizes that parties can contractually assume a duty, Plaintiffs argue that Statprobe is bound by its contractual assumption of a duty to the public.

Finally, Plaintiffs argue that Statprobe conspired with Gliatech to withhold accurate data

<sup>11</sup> Statprobe notes that Plaintiffs did not specifically allege "negligent undertaking" in their Complaint, but have only added it as an "afterthought."

from the FDA and, therefore, Plaintiffs have a valid civil conspiracy<sup>12</sup> claim against Statprobe.

At this early stage, dismissal of the negligence claim for failing to show a duty would be improper. While it is true that laboratories are rarely found to have a duty to a third party, the facts here are unique in that Statprobe appears to be more intimately involved than a typical clinical data researcher and analyst and the facts alleged do articulate allegations that Statprobe participated in misleading the FDA and, by extension, the public about the efficacy of ADCON-L. While Statprobe raises an innovative argument that its work related to the effectiveness of the product versus the actual harm alleged, this argument requires the Court to evaluate facts and make conclusions of fact that are premature at this time. The question for the Court is whether Plaintiffs alleged any set of facts, making all reasonable inferences in favor of Plaintiffs, that could support a conclusion that Statprobe had a duty to Ms. Wawrynek.

Statprobe asserts that Plaintiffs failed to raise the theories of negligence which Plaintiffs rely on in their response to the Motion to Dismiss. Given the standards of notice pleading and considering the Complaint here, Statprobe was on notice that the negligence claim was based on the theories of negligent misrepresentation and negligent undertaking. While these precise terms are not explicitly mentioned in the Complaint, the Complaint clearly alleges facts that would support such theories. Plaintiffs allege that Statprobe gave “false information” to the FDA and the public and that Ms. Wawrynek’s physical harm, as a third person reasonably expected “to be put in peril by the action taken,” was caused by the FDA’s and public’s reasonable reliance on

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<sup>12</sup> Civil conspiracy requires “that two or more persons combine or enter an agreement to commit an unlawful act or to do an otherwise lawful act by unlawful means... Proof of malice is an essential part of a cause of action for conspiracy.” Burnside v. Abbott Laboratories, 505 A.2d 973, 980 (Pa. Super. Ct. 1985).

data ostensibly published by Statprobe or with Statprobe's knowledge, namely the use of the drug following surgery. (Pls.' Compl., at ¶ 54); see also RESTATEMENT (SECOND) OF TORTS § 311. Similarly, Plaintiffs explicitly allege that Statprobe "knew when it substituted false data to gain approval for ADCON-L that this product would be used in patients by physicians both of whom would rely on [Statprobe's] honesty and integrity." (Pls.' Compl., at ¶ 52). This paragraph, along with other similar averments in the Complaint, have placed Statprobe on notice that Plaintiffs are claiming that the services undertaken by Statprobe on behalf of Gliatech were "services... which [Statprobe] should recognize as necessary for the protection of a third person." RESTATEMENT (SECOND) OF TORTS § 324(a). The mere failure to use the exact legal term for a theory, while amply providing a factual basis for the theory, is not grounds for a federal court to deny the party access to that theory. FED. R. CIV. P. 8. As such, it is clear that Plaintiffs have alleged facts sufficient to place Statprobe on notice of the negligent misrepresentation and the negligent undertaking theories. Plaintiffs have alleged facts sufficient, under these theories, to proceed with the claim that Statprobe had a duty to Ms. Wawrynek. Therefore, the Motion to Dismiss is denied as to the negligence claim.

V. **CONCLUSION**

For the foregoing reasons, the Court grants in part and denies in part the Defendant's Motion to Dismiss. The Motion is granted as to Count Three, the breach of contract claim. The Motion is denied as to all other Counts. An appropriate Order consistent with this Memorandum follows.

BY THE COURT:

/S/  
GENE E. K. PRATTER  
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

EILEEN WAWRZYNEK and	:	CIVIL ACTION
JOSEPH WAWRZYNEK,	:	
Plaintiffs	:	
	:	
v.	:	
	:	
STATPROBE, INC., <i>et al</i> ,	:	
Defendants	:	NO. 05-1342

**O R D E R**

Gene E.K. Pratter, J.

September 2, 2005

AND NOW, this 2<sup>nd</sup> day of September, 2005, upon consideration of Defendants' Motion to Dismiss (Docket No. 5), Plaintiffs Eileen Wawrzynek's and Joseph Wawrzynek's Memorandum of Law in Support of its Response (Docket No. 6), Defendants' Reply (Docket No. 8), and the arguments of counsel at oral argument held on June 29, 2005, it is hereby ORDERED that the Motion to Dismiss is GRANTED IN PART and DENIED IN PART. The Motion is GRANTED as to Count Three: Breach of Contract. The Motion is DENIED as to all other Counts.

BY THE COURT:

/S/  
\_\_\_\_\_  
GENE E. K. PRATTER  
UNITED STATES DISTRICT JUDGE